

**BRS Stakeholder
Updates**

Sent by: Judy A Garrison

To:

cc:

Subject: BRS Stakeholder Update

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April 27, 2005

Dear BRS Stakeholder:

The last time the U.S. Department of Agriculture's (USDA) Biotechnology Regulatory Services (BRS) sent out a Stakeholder Update, it was to announce plans to review and strengthen our existing biotechnology regulations. The first step in that process—conducting a draft Environmental Impact Statement (EIS)—is well underway. I wanted to take this opportunity to provide you with an update on the status of the draft EIS and to let you know that we've launched a Web site dedicated entirely to the programmatic review we're currently undertaking. While a review of this magnitude takes time, I'm confident that the resulting final rule will position BRS for the future and ensure that our regulations address the latest science biotechnology has to offer.

As our regulations evolve to keep pace with biotechnology, we're making some changes with our internal organization as well. Our staff continues to expand and these new changes reflect BRS' developing program functions and growth in funding and infrastructure over the past two years. Also in this Update, you'll find information about two public forums BRS is holding in May to get feedback from our stakeholders and the public on a new variety of genetically engineered (GE) creeping bentgrass. I encourage anyone who can to attend and provide official comment.

In addition to updating you on these program activities, I also wanted to inform you of a key new leadership position in BRS. It's just one more example of how BRS continues to grow and change in order to respond to increasing program responsibilities. Finally, in order to ensure that you continue to receive the latest stakeholder information, I wanted to make you aware that BRS has a new on-line registry for stakeholders. This is the last Update that will be sent out under the old format, so please take advantage of our new Stakeholder Registry so that you continue to receive the latest BRS news and information.

I hope you find our program activities and growth as exciting as I do. As always, I welcome and value your input and perspectives.

Sincerely,

Cindy Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service

BRS Stakeholder Update

EIS Information Web site

The current programmatic review of BRS' existing biotechnology regulations is the largest effort of its kind since the Coordinated Framework for biotechnology regulations was first established in 1986. As such, BRS has created a comprehensive Web site to keep our stakeholders and the public informed as the review process progresses. We've established an ambitious timeline for completing the comprehensive draft EIS and hope to publish the document in the Federal Register this fall. In the meantime, you can keep abreast of the issues we're reviewing by going to: <http://www.aphis.usda.gov/brs/eis/index.html>.

The site describes all the steps in the EIS process, beginning with scoping, which resulted in more than 2,000 public comments. Those public comments as well as comments received during several stakeholder meetings are all accessible on the new Web site. In addition, the site contains information about the various sections of the draft EIS, the issues under consideration in the document and background on the regulation of biotechnology. The site also announces an additional mechanism for input regarding the EIS. BRS will be setting aside one day per month to meet with interested stakeholders and the public to continue the dialogue we initiated during our March 2004 stakeholder listening sessions. This new site is extremely comprehensive and will continue to be updated throughout the review process, so add it to your favorites and check it regularly!

BRS Reorganization

Since BRS was first created in June 2002, a lot of changes have taken place. The program has grown from a staff of 25 to more than 50 employees. We've made some dynamic changes to our organizational structure in order to address emerging needs, support key functions and anticipate future growth. I'd like to highlight four critical areas, including, the creation of a division dedicated to Environmental Risk Analysis (ERA). This new division will conduct environmental risk analyses, which provide the scientific foundation of our regulatory activities and ensure protection of agriculture and the environment. ERA will be divided into 3 branches that will focus on transgenic animals, plants, and plant pests and protectants.

The creation of BRS' new Regulatory Operations Programs will allow for greater emphasis on compliance and documents management. The division will support dedicated compliance and oversee field test inspections, audits, record keeping and other related activities to ensure that companies, universities and other researchers conducting field tests adhere to the stringent planting conditions required by BRS. This division will also conduct concerted outreach activities to ensure researchers are fully aware of APHIS' regulatory scope and their regulatory obligations.

Under BRS' Policy Coordination Programs, BRS is continuing to build key international functions, including standard-setting for biotechnology regulations that appropriately reflect the latest science. The newly established Communications and Capacity Building Branch will

ensure that educational programs focusing on science-based biotechnology, regulatory frameworks and risk assessment are conducted domestically as well as internationally.

BRS' Office of Science will help support all of these program functions by acting as a focal point for access to the latest science related to biotechnology. The resources of the Office of Science will ensure that all of BRS' regulatory and policy decisions are based on the most current scientific thinking and that this information is available to our State and international partners.

Creeping Bentgrass Public Forums

In 2003, Monsanto Company and Scotts Company submitted a petition to BRS to deregulate a new variety of GE herbicide tolerant creeping bentgrass. Since that time, BRS has published notice that the program is preparing an EIS to consider any environmental effects associated with granting non-regulated status to this new GE variety. If granted, the bentgrass variety could be sold and grown in the U.S. without further BRS oversight.

As a follow up to that announcement, BRS is holding two public forums to accept public comment on the new GE variety. The comments that we receive during these forums and the comments that we have already received through the Federal Register will all be taken into consideration as BRS prepares the draft EIS. The first forum will be held on May 3, 2005, at the National 4-H Youth Center in Chevy Chase, MD. The second forum will take place on May 18, 2005, at the Oregon State University Conference Complex in Corvallis, OR. Oregon was selected as one of the locations because much of the United States commercial bentgrass production occurs there.

These public forums are important because they allow BRS to hear directly from our stakeholders and the public. BRS would like to be as transparent as possible as we begin this review process and these forums provide an opportunity to solicit input from producers, industry, non-governmental organizations and others interested in biotechnology. For complete information about the two forums, including addresses and times, go to:

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2005_register&docid=fr11ap05-44.

This link will take you to the April 11, 2005, Federal Register notice that first announced the 2 forums.

New BRS Leadership Position

I'm pleased to announce that Rebecca Bech has been selected as BRS' Associate Deputy Administrator for Emerging and International Programs. This is a new senior executive position established by USDA's Animal and Plant Health Inspection Service (APHIS) to provide BRS with a second Associate Deputy position—one that will focus on building new programs and establishing new initiatives policies and regulations to meet the evolving nature of APHIS' biotechnology regulatory framework. This position will also be responsible for advancing these initiatives and regulatory models within the international biotechnology arena as appropriate.

Since BRS' creation, Rebecca has provided strong leadership and direction, having served

effectively in multiple high-level management positions including Associate Deputy Administrator, Acting Policy Coordination Division Director and Acting Regulatory Division Director. In these positions, Rebecca played key roles in strengthening USDA's regulation of plant-based pharmaceuticals and plant-based industrials, restructuring BRS' compliance and enforcement policies and providing leadership on international activities. In the very near future, BRS will be advertising the Associate Deputy vacancy created by Rebecca's promotion. This GS-15 position is dedicated to the management of existing BRS programs.

Stakeholder Registry

In addition to receiving BRS' Stakeholder Updates, our new Stakeholder Registry will allow you to receive information based on selected topics of interest, including biotechnology goals, regulatory activities and revisions, capacity building, and compliance issues to name just a few. This registry is a centralized on-line system accessible via the BRS website at: <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf>. Information presented on the Web site will be secured through the use of a username and password as well as data encryption. Registered stakeholders will be allowed to update their information by entering their username and password. The advantages to the new on-line registry include centralized stakeholder information, targeted information to interested parties, and enhanced security features.

In order to receive future stakeholder updates and other information relevant to selected topics of interest, all stakeholders currently receiving BRS stakeholder updates will need to register for the new Stakeholder Registry. As always, we welcome any comments or suggestions regarding the new Stakeholder Registry, and ask that you email them to David.G.Bennett@aphis.usda.gov.